STATE PROCUREMENT OFFICE

NOTICE & REQUEST FOR SOLE SOURCE

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STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health/State Laboratories/Medical Microbiology Branch
Name of Requesting Department

Pursuant to HRS §103D-306 and HAR chapter 3-122, Subchapter 9, the Department requests sole source approval to purchase the following:

1. Describe the goods, services, or construction to be procured.
Laboratory Test Kits & Accessories based on nucleic acid amplification procedures, target capture and dual kinetic assay.

2. Vendor/Contractor/Service Provider Name:	3. Amount of Request:
~~GEN-PROBE, INC.~~ GEN-PROBE SALES & SERVICE, INC. SSN 6/18/13	$500,000.00
4. Term of contract (shall not exceed 12 months), if applicable: From: 7/1/2013 To: 6/30/2014	5. Prior SPO-001, Sole Source (SS) No.: 12-069D/Ka1

6. Describe in detail the following:

a. The unique features, characteristics, or capabilities of the goods, service or construction.

Our equipment and software is proprietary to Gen-Probe, Inc. No other test kits are compatible with our instrumentation. The test kits are designed to provide laboratory evidence of infection by microbial agents. The analytical method used in these kits are based on a concept termed target capture to yield the analyte to be amplified. The amplification procedure increases the sensitivity, which is the ability of the assay to detect small amounts of genetic material, which could lead to false positive findings.

Genetic material such as DNA and RNA are unique to each species of microbial agents. These kits are specifically prepared segments of genetic materials linked to a chemical marker. Genetic material recovered from patient's specimens are prepared and allowed to react with the prepared segments. In the event (see attached sheet)

b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department

Our current system, was upgraded to the PANTHER System in September 2012, allows us to use both individual nucleic acid assays and a dual kinetic design which allows for the simultaneous detection and identification of both Chlamydia trachomatis and Neisseria gonorrhoeae. All other US FDA approved test kits require the performance of individual assays or detection procedures to achieve that result. These products are also approved for longer specimen transport and storage period of time than any other product. All other known products require testing within 7 - 30 days of collection and these products allows the specimen to be tested, if stored properly, up to 60 days after collection. (Stability studies performed by the manufacturer have shown that female swab specimens and male and female urine specimens may be frozen up to 12 months, while male urethral swabs may be stored for up to 6 months from the date of collection.) This property is an essential consideration, especially with the transport times from neighbor island facilities and other jurisdictions requiring longer transport times. (see attached sheet)

7. Describe the efforts and results in determining that this is the only vendor/contractor/service provider who can provide the goods, services or construction.

See the Attached Letter from Gen-Probe.

8. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.

No other manufacturer is able to provide the technology. Individual nucleic acid assays from other manufacturers and Gen-Probe have been reviewed and found to be too labor intensive and costly to implement. The specimen transport time for all other US FDA approved products are limited to 7 days and up to 30 days for some type of specimens from date of collection. The current equipment is only compatible with reagent test kits using the Gen-Probe Aptima technology.

9. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required.)
*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	E-mail Address
Gail Kunimoto	*SLD/MMB*	*453-6700*	*gail.kunimoto@doh.hawaii.gov*

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR chapter 3-122, Subchapter 15, Cost or Pricing Data if required.

All requirements/approvals and internal controls for this expenditure is the responsibility of the department. I certify that the information provided is to the best of my knowledge, true and correct.

Department Head Signature

6/7/13
Date

For Chief Procurement Officer Use Only

Date Notice Posted: 6/12/13

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is for the period 07/01/13 to 06/30/14 and is based on the department's representation that the laboratory test kits and accessories are only available for sale by Gen-Probe Sales & Service, Inc. Sole source contracts in excess of $100,000 require cost or pricing data pursuant to HAR chapter 3-122, subchapter 15. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System. Copies of the cost or pricing data, HCE certificate and awards posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Stanton Mato at 586-0566, or stanton.d.mato@hawaii.gov.

☒ Approved ☐ Disapproved ☐ No Action Required

Chief Procurement Officer Signature *Date* 6/12/2013

6. Describe in detail the following:

   a. The unique features, characteristics, or capabilities of the goods, services, or construction.(continued)

      the prepared segments and the isolate's segments match, a binding occurs, and through the use of a chemical reaction, a positive signal is sent to an instrument. In the event of a non-match, no binding occurs and no chemical reaction occurs and a negative response is sent to an instrument. A positive signal is an indication of the identity of the organism. The procedure, since it uses specific genetic material from known organisms and the binding phenomenon is unique for each specimen, produces highly accurate results. The use of this procedure is rapid and accurate.

      This method is highly sensitive and specific. Due to the use of instrumentation and known reagents based on genetic material, the reagents are objective and highly accurate. The use of these kits allow for the rapid diagnosis of patients, however, without the ability to recover the organism.

      The dual kinetic assay allows for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) on one test run. This is accomplished through the use of dissimilar kinetic detection systems. This dual system reduces the amount of time compared with the requirement of conducting assay methods specific for these agents. In essence, this one procedure allows the detection or absence and identification of both agents, without additional testing. Since the test is based on unique genetic properties of the organisms, no additional confirmatory testing is required.

   b. How the unique features, characteristics, or capabilities of the goods, services or construction are essential for the department (continued)

      The availability of a urine transport system, which will reduce the possibility of cross contamination, also provides the ability to test non-invasive specimens. This will allow for testing of patients from areas where the collection of specimens requiring invasive procedures is not available.

      These products are also the only known US FDA approved products that allow for testing of patient and physician collected vaginal specimens, in addition to female endocervical and male urethral specimens. This will allow the Department's disease control program to evaluate the incidence of disease in geographic areas that have not been tested.

      After the PANTHER System upgrade, our laboratory successfully performed off-label validation of the assay with male and female urines, oral and rectal GC specimens and rectal CT specimens.

We were able to perform the off-label oral-rectal validations with the assistance of the Centers for Disease Control and Prevention (CDC) and the San Francisco Public Health Laboratory (SFPHL). Our laboratory will perform the off-label oral CT specimens when the verification panel becomes available.